Remarks

Claim Objections

Claim 1 was objected to because "polymeric carrier" was written in singular but should be written in the plural for consistency with the remainder of the claim. Claim 1 was further objected to because the phrase "penetrated into" was not grammatically correct, as it was not followed by a recitation of what is penetrated. Claim 35 was objected to because the term "penetrated" was added to replace the term "accessed", but "accessed" was not deleted from the claim. Applicants respectfully traverse these objections to the extent that it is applied to the claims as amended.

Claim 1 has been amended to specify that the agent is delivered in a polymeric carrier selected from the group consisting of porous matrices, hydrogels, organogels, colloidal suspensions, microparticles and microcapsules, nanoparticles and combinations thereof. The term polymeric carrier is now grammatically correct as written in singular form. Claim 1 has been further amended by rephrasing of the claim to specify that the method of treatment comprises penetrating into the endomural zone of an organ, organ component or tissue structure. Thus, claim 1 now clearly indicates what is penetrated. Claim 35 has been amended to delete the term "accessed".

Rejection Under 35 U.S.C. § 112, first paragraph (written description)

Claims 1, 3, 6, 7 and 13-24 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed

invention. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

The Legal Standard

The first paragraph of Section 112 provides that the "specification shall contain a written description of the invention..." 35 U.S.C. § 112 (2005). "The description requirement's purposes are to assure that the applicant was in full possession of the claimed subject matter on the application filing date and to allow other inventors to develop and obtain patent protection for later improvements and subservient inventions that build on applicant's teachings." 3-7 Chisum on Patents § 7.04 (2005), citing *Fields v. Conover*, 443 F.2d 1386, 170 U.S.P.Q. 276 (CCPA 1971).

The general standard for the written description requirement is that "a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." *See* M.P.E.P. § 2163(I). Possession may be shown in many ways. For example, possession may be shown by describing an actual reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Id.*, citing *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000); *Pfaff v.*

Wells Electronics, Inc., 55 U.S. at 66, 119 S.Ct. at 311, 48 USPQ2d at 1646. As noted in a recent decision by the Board of Appeals and Interferences, the written description requirement does not require a description of the complete structure of every species within a chemical genus. (*see Utter v. Hiraga*, 845 F.2d 993, 998, 6 U.S.P.Q.2d 1709, 1714 (Fed. Cir. 1988), stating "A specification may, within the meaning of 35 U.S.C. § 112, para. 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses.").

A specification may describe an actual reduction to practice by showing that the inventor constructed *an embodiment* or performed *a process* that met all the limitations of the claim and determined that the invention would work for its intended purpose. *Cooper v. Goldfarb*, 154 F.3d 1321, 1327, 47 USPQ2d 1896, 1901 (Fed. Cir. 1998) (emphasis added). Although reduction to practice often provides the best evidence that an invention is complete, actual reduction to practice is not required by the written description requirement. An applicant may show possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

In *Falkner*, the Federal Circuit recently addressed the issue of written description in an appeal from an interference. *Falkner v. Inglis*, 448 F.3d 1357, 79 USPQ2d 1001 (Fed. Cir. 2006). The issue was whether the applicant's priority applications adequately described and enabled a poxvirus-based vaccine. The Federal Circuit reiterated that "[t]he 'written description requirement implements the principle that a patent must describe the technology that is sought to

be patented; the requirement serves to demonstrate that the patentee was in possession of the invention that is claimed." *Falkner* at 1366. The Federal Circuit also clarified that with regard to the written description requirement: (1) examples are not necessary to support the adequacy of the a written description; (2) the written description standard may be met even where actual reduction to practice of an invention is absent; and (3) there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure. *Falkner* at 1366.

Analysis

Independent claims 1 and 15 are amended to specify that the therapeutic, prophylactic or diagnostic agent is delivered in a *polymeric* carrier selected from the group consisting of porous matrices, hydrogels, organogels, colloidal suspensions, microparticles and microcapsules, nanoparticles and combinations thereof. Support for this amendment may be found at least in claim 5 as originally filed, at page 8, lines 16-30, page 12, lines 3-30, page 14, lines 4-21, and at page 23, lines 6-18.

According to the Examiner's own admission, and at least at the passages indicated above, the specification discloses that therapeutic, prophylactic and diagnostic agents can be delivered to the endomural zone using polymers. Additionally, claim 5 as originally filed discloses that polymers may be in the form of porous matrices, hydrogels, organogels, colloidal suspensions, microparticles and microcapsules, nanoparticles and combinations thereof.

The Examiner alleges that although the specification discloses the use of polymers to deliver therapeutic, prophylactic and diagnostic agents to the endomural zone, it does not teach

that these structures are intended as *carriers*. Contrary to this assertion by the Examiner, the specification does indeed provide significant disclosure in this regard. For example, on page 8, at lines 16-30, the specification discloses that polymers may "contain embedded or grafted bioactive molecules, peptides, lipids, drugs or other moieities." One of ordinary skill in the art would interpret the phrase "contain embedded or grafted" to mean that the polymers are serving as carriers for these agents. Further, on page 23, at lines 6-18, the specification discloses that "a wide variety of bioactive agents can be incorporated into the polymeric material." Again, one of ordinary skill in the art would interpret the phrase "incorporated into the polymeric material" to mean that the polymeric material is functioning as a carrier for the bioactive agent. The specification on page 23, at lines 6-18, further provides disclosure regarding how bioactive agents can be incorporated and how they are released from the polymeric carrier material. Thus, one of skill in the art would recognize that the inventors were in possession of the claimed subject matter at the time the application was filed.

Rejection Under 35 U.S.C. § 112, second paragraph

Claims 14, 18, 19 and 34 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

The Legal Standard

The second paragraph of 35 U.S.C. § 112 states that the claims must particularly point out and distinctly claim the subject matter regarded as the invention. The Applicant may use functional language, alternative expressions, negative limitations or any style of expression or

format of claim which makes clear the boundaries of the subject matter for which protection is sought (MPEP 2173.01). The MPEP further states that while the "Examiner is encouraged to suggest claim language to applicants to improve the clarity or precision of the language used" they "should not reject claims or insist of their own preferences if other modes of expression selected by applicants satisfy the statutory requirement" (MPEP 2173.02).

"Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

(A) The content of the particular application disclosure;

(B) The teachings of the prior art; and

(C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore serves the notice function required by 35 U.S.C. 112, second paragraph. " (MPEP 2173.03 citing *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000). As noted in the court in *In re Swinehart*, 439 F.2d 210, 160 USPQ 226 (CCPA 1971), a claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought.

Analysis

Claims 14 and 34

Claims 14 and 34 have been cancelled. Therefore the rejection of these claims under 35 U.S.C. § 112, second paragraph is rendered moot.

Claim 18

Independent claim 15 has been amended to specify that the device comprises a means for local delivery of a therapeutic, prophylactic or diagnostic agent into a void, cavity, containment space or reservoir area in the endomural zone of an organ, organ component or tissue structure. Claim 18, which depends from claim 15, has been amended to specify that the means for local delivery of a therapeutic, prophylactic or diagnostic agent comprises a single or multiple reservoirs attached to the member. Claim 18, as amended, clearly defines a reservoir or reservoirs as components of a means for local delivery of the agent as specified in claim 15. Therefore, claim 18 as amended, is definite.

Claim 19

Independent claim 15 specifies that the device comprises a means for creating a void, cavity, containment space or reservoir area in the endomural zone of an organ, organ component or tissue structure. Claim 19, which depends from claim 15, has been amended to specify that the means to create a void, cavity, containment space or reservoir area comprises an expansile cutter attached to an end of the member. Claim 19, as amended, clearly defines an expansive cutter as a means to create a void, cavity, containment space or reservoir area as specified in claim 15. Therefore, claim 19, as amended, is definite.

Rejection Under 35 U.S.C. § 102

Claims 1, 3, 4, 6, 7, 15-18, 20-23, 25, 28, 29, 32 and 35-37 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,585,716 by Altman ("the '716 patent"). Claims 1, 3, 6, 7, 15-18, 19, 21-23, 25, 34, 36 and 37 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,102,887 by Altman ("the '887 patent"). Claims 1, 3, 4, 6, 7, 14-16, 18, 20-24, 32 and 34-37 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,309,370 by Haim, *et al.* ("the '370 patent"). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

The Legal Standard

For a rejection of claims to be properly founded under 35 U.S.C. § 102, it must be established that a prior art reference discloses each and every element of the claims. *Hybritech Inc. v Monoclonal Antibodies Inc.*, 231 USPQ 81 (Fed. Cir. 1986), cert. denied, 480 US 947 (1987); Scripps Clinic & Research Found v. Genentech Inc., 18 USPQ2d 1001 (Fed. Cir. 1991). The Federal Circuit held in Scripps, 18 USPQ2d at 1010:

> Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. . . There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. (Emphasis added)

A reference that fails to disclose even one limitation will not be found to anticipate, even if the missing limitation could be discoverable through further experimentation. As the Federal Circuit held in Scripps, Id.:

> [A] finding of anticipation requires that all aspects of the claimed invention were already described in a single reference: a finding that is not supportable if it is necessary to prove facts beyond those disclosed in the reference in order to meet the claim limitations. The role of extrinsic evidence is to educate the decision-maker to what the reference meant to persons of ordinary skill in the field of the invention, not to fill in the gaps in the reference.

For a prior art reference to anticipate a claim, it must enable a person skilled in the art to practice the invention. The Federal Circuit held that "a §102(b) reference must sufficiently describe the claimed invention to have placed the public in possession of it. . . [E]ven if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling." Paperless Accounting Inc v Bay Area Rapid Transit Sys., 231 USPQ 649, 653 (Fed. Cir. 1986).

Analysis

Independent claims 1 has been amended to specify that the method of treatment comprises cutting or removing tissue in the endomural zone to create a void, cavity, containment space or reservoir area. Claim 1 has been further amended to specify that the therapeutic, prophylactic or diagnostic agent is delivered to the void, cavity, containment space or reservoir area in the endomural zone. Support for these amendments can be found in the specification at least at the paragraph bridging pages 11 and 12 and in claim 14 as originally filed. Claim 15 and 25 are amended to specify that the device and kit comprise an end means for penetrating into the endomural zone of an organ, organ component or tissue structure and a means for creating a

void, cavity, containment space or reservoir area in the endomural zone by cutting or removal of tissue. Support for this amendment may be found in the specification at least at the paragraph bridging pages 11 and 12 and in claim 14 as originally filed.

The '716 patent

The '716 patent describes methods for treating the human heart. A guide catheter is placed in the venous portion of a patient's vasculature and extends until the vena cava and coronary sinus. A drug delivery catheter is inserted inside the guide catheter and extends beyond the guide catheter so that the tip enters the cardiac vein and extends to the posterior vein. The tip contains a penetrating element, such as a curved or helical needle, that is selectively extended into the wall of the vein and into the myocardium. Therapeutic agents are injected into the myocardium, through the needle (col. 4, lines 5-19 and Figure 1). The guide catheter contains an occluding mechanism. The venous flow path is shut off by occluding the coronary ostium with the occluding mechanism. This stops the natural blood flow from the myocardium into the vein, thereby preventing the therapeutic agents from being flushed out of the myocardium in the course of normal blood flow. (col. 4, lines 20-47)

The '716 patent does not disclose forming a void, cavity, containment space or reservoir area in the endomural zone as required by amended claims 1, 15 and 25. The '716 patent merely uses a catheter which is inserted between cells into the heart tissue for delivery of drug to the vasculature within the heart. This is a pre-existing structure. There is no teaching to create a new void, cavity, containment space or reservoir area by cutting or other means permanently removing the tissue. Insertion of a needle or catheter does not create a void as claimed, but

merely pushes aside tissue which refills the temporary displacement upon removal of the device. Catheters and needles do not cut or remove tissue; they simply displace it.

Therefore, claims 1, 3, 4, 6, 7, 15-18, 20-23, 25, 28, 29, 32 and 35-37 are novel over the '716 patent.

The '887 patent

The '887 patent describes a steerable catheter with a deployable penetrating element, such as a helical or straight needle, for administration of drugs to the heart (col. 3, lines 9-22). Agents can be delivered in microformulations such as microspheres, nanoparticles or polymers. The claims, as amended require creating a void, cavity, containment space or reservoir area in the endoluminal zone by cutting or removal of tissue. The '887 patent merely uses a catheter with a distensible needle for delivery of drugs to the myocardium of the heart. There is no teaching to create a new void, cavity, containment space or reservoir area by cutting or any other means which permanently remove the tissue. As discussed above with respect to the '716 patent, insertion of a needle or catheter does not create a void as claimed, but merely pushes aside tissue which refills the temporary displacement upon removal of the device. Catheters and needles do not cut or remove tissue; they simply displace it.

Col. 9, lines 20-52 discloses an expanding prong *fixation* system, which may be used to *stabilize* the needle, *not* to create a void, cavity, containment space or reservoir as required by independent claims 1, 15 and 25. Merriam-Webster defines "void" as "not occupied" or "containing nothing" (*see* definition attached). Merriam-Webster also defines "cavity" as "an unfilled space within a mass" (*see* definition attached). The instant claims require the formation

of such an "*unfilled* space", into which the therapeutic, prophylactic or diagnostic agent is delivered. Although the prong fixation system disclosed in the '887 patent is able to penetrate body tissue, this merely creates a cut in the tissue which is *occupied*, or *filled* with the prongs. The fixation system is designed to stay in place as the agent is delivered. The '887 patent does not disclose retracting the prongs prior to delivery of an agent. Thus, the prongs of the fixation system disclosed in the '887 patent do not create a void, cavity, containment space or reservoir into which the agent is delivered. Therefore claims 1, 3, 6, 7, 15-18, 19, 21-23, 25, 34, 36 and 37 are novel over the '887 patent.

The '370 patent

The '370 patent discloses a method and device for delivery of growth factors to an ischemic region in the heart. The '370 patent emphasizes the importance of navigating the catheter to the site of the ischemic regions (see col. 4, lines 25-40). The device is a catheter that contains sensors to determine the position of the catheter with respect to the heart wall (col. 12, lines 10-28). When the device is in place, the needle is placed inside the heart wall and the growth factors are delivered (see e.g. col. 12, lines 40-49 and col. 13, lines 39-50 and col. 14, lines 3-11). The growth factors may be administered in a solution or a capsule (see col. 15, lines 14-20).

As discussed above with respect to the '716 and '887 patents, the '370 patent does not disclose forming a void, cavity, containment space or reservoir area in the **endomural** zone, as required by amended claims 1, 15 and 25. The '370 patent merely uses a catheter for delivery of drug to the vasculature within the heart.

Rejection Under 35 U.S.C. § 103

Claims 13 and 33 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,585,716 by Altman ("the '716 patent") or U.S. Patent No. 6,102,887 by Altman ("the 887 patent) or U.S. Patent No. 6,309,370 by Haim, *et al.* ("the '370 patent"), in view of Benjamin and McMillan, *Circ. Res.*, 83:117-132 (1988) ("Benjamin and McMillan"). Claim 31 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Brosamle, *et al.*, The Journal of Neuroscience, 20(21):8061-68 ("Brosamle") in view of U.S. Patent No. 6,585,716 by Altman ("the '716 patent") or U.S. Patent No. 6,102,887 by Altman ("the 887 patent) or U.S. Patent No. 6,309,370 by Haim, *et al.* ("the '370 patent"). Applicants respectfully traverse these rejections to the extent that they ar applied to the claims as amended.

The Legal Standard

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

"There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary

skill in the art." In re Rouffet, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998) (The combination of the references taught every element of the claimed invention, however without a motivation to combine, a rejection based on a prima facie case of obvious was held improper.). The level of skill in the art cannot be relied upon to provide the suggestion to combine references. Al-Site Corp. v. VSI Int'l Inc., 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999).

To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Analysis

Independent claims 1 has been amended to specify that the method of treatment comprises cutting or removing tissue in the endomural zone to create a void, cavity, containment space or reservoir area. Claim 1 has been further amended to specify that the therapeutic, prophylactic or diagnostic agent is delivered to the void, cavity, containment space or reservoir area in the endomural zone. Support for these amendments can be found in the specification at least at the paragraph bridging pages 11 and 12 and in claim 14 as originally filed. Claim 15 and 25 have been amended to specify that the device and kit comprise an end means for penetrating into the endomural zone of an organ, organ component or tissue structure and a means for

creating a void, cavity, containment space or reservoir area in the endomural zone by cutting or removal of tissue. Support for this amendment may be found in the specification at least at the paragraph bridging pages 11 and 12 and in claim 14 as originally filed.

Claims 13 and 33

Claim 13 is a method claim that depends from claim 3 and further defines the therapeutic agent as a heat shock proteins, stress response proteins, or inducers of heat shock or stress response proteins. Claim 33 is a kit claim that depends from claim 25 and further defines the kit as containing stress response inducing agents or stress response proteins.

The combination of the '716, '887, or '370 patents with Benjamin

As noted above, none of the '716, '887 or '370 patents disclose a means for forming a void, cavity, containment space or reservoir area in the endomural zone by cutting or removing tissue. Additionally, the '370 patent does not disclose including a void filling material or implant in the device.

Benjamin is a general reference about heat shock proteins and some of their roles. Benjamin does not cure the deficiencies of the '716, '887, and '370 patents. The combination of these references still does not disclose or suggest delivering heat shock proteins, stress response proteins, and inducers of heat shock or stress response proteins into a void, cavity, containment space or reservoir area created by cutting or removal of tissue as defined by claim 13. Additionally, the combination of Benjamin with the '716, '887, and '370 patents does not disclose a kit containing a void filling material or implant in a form suitable for local administration, as required by claim 33.

Claim 31

Claim 31 is device claim that depends from claim 15 and further defines the device as being suitable for nerve regeneration.

The combination of Brösamle with Altman '716, Altman '887, or Haim

As noted above, the '716, '887 and '370 patents do not disclose forming a void, cavity, containment space or reservoir area in the endomural zone by cutting or removing tissue, as required by claim 31. Brösamle describes administering an antibody to the spinal cord to promote regeneration. Brösamle does not cure the deficiencies of the '716, '887 or '370 patents. Brösamle does not disclose a device with means for for creating a void, cavity, containment space or reservoir area. Therefore the combination of Brösamle with the '716, '887, or '370 patents does not make claim 31 obvious.

Allowance of claims 1, 3, 6, 7, 13, 15-25, 28, 29, 31-33 and 35-37 is respectfully solicited.

Respectfully submitted,

/ Patrea L. Pabst /

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void

4 entries found for **void**.
To select an entry, click on it.

void[1,adjective]
void[2,noun]
void[3,verb]
null and void

Go

Main Entry: **[1]void**
Pronunciation: 'void
Function: *adjective*
Etymology: Middle English *voyde*, from Anglo-French, from Vulgar Latin **vocitus*, alteration of Latin *vocivus, vacivus* empty, from *vacare* to be empty
1 a : not occupied : VACANT <a *void* bishopric> **b :** not inhabited : DESERTED
2 : containing nothing <*void* space>
3 : IDLE, LEISURE
4 a : being without something specified : DEVOID <a nature *void* of all malice> **b :** having no members or examples; *specifically of a suit* : having no cards represented in a particular hand
5 : VAIN, USELESS
6 a : of no legal force or effect : NULL <a *void* contract> **b :** VOIDABLE
synonym see EMPTY
- void·ness *noun*